The Children's Hospital of Philadelphia®
RESEARCH INSTITUTE

INSTITUTIONAL REVIEW BOARD

Date: 6/6/2018

To: Jeffrey Gerber
CC: Nicole Frager
From: The Committees for the Protection of Human Subjects (IRB)

Re: IRB 18-015165, **Protocol Title:** A novel Metric for Benchmarking Antibiotic Use to Inform Outpatient Stewardship
Sponsor or Funder: N/A

IRB SUBMISSION: DETERMINATION OF NOT HUMAN SUBJECTS RESEARCH

Dear Dr. Gerber,

The IRB acknowledges receipt of the above-referenced proposal. This proposal was reviewed on 6/6/2018. It has been determined that the proposal does not meet the criteria for human subjects research (see below) and, therefore, ongoing IRB oversight is not required.

PLEASE NOTE: A determination of not human subjects research by the IRB does not necessarily constitute authorization to initiate the project. The Investigator is responsible for satisfying any additional institutional requirements that may apply (e.g. execution of the appropriate agreement with the Office of Technology Transfer for sending or receiving data or samples, etc.).

Documents Reviewed:

- Study Summary (attached May 18, 2018)
- DBHi Honest Broker Letter (dated June 1, 2018)

Please refer to the eIRB application for a complete list of all documents submitted to the IRB.

This proposal does not meet the following regulatory definitions of human subjects research:
Does not meet the definition of "human subject": According to 45 CFR 102(f), "Human subjects means a living individual about whom an investigator (whether professional or student) conducting research obtains:

(1) data through intervention[1] or interaction[2] with the individual, OR
(2) identifiable private information

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[1]Intervention includes both physical procedures by which data are gathered (for example, venipuncture) and manipulations of the subject or the subject's environment that are performed for research purposes.
[2]Interaction includes communication or interpersonal contact between investigator and subject.

* Private information includes information about behavior that occurs in a context in which an individual can reasonably expect that no observation or recording is taking place, and information which has been provided for specific purposes by an individual and which the individual can reasonably expect will not be made public (for example, a medical record). Private information must be individually identifiable (i.e. the identity of the subject is or may be readily ascertained by the investigator or associated with the information) in order for obtaining the information to constitute research involving human subjects.

Please note: It is the responsibility of the Principal Investigator to communicate any changes in the proposal to the IRB, including the use or incorporation of other data sets which may not be de-identified or publicly available. If you wish to change any aspect of this study, a new proposal will need to be submitted for review. New procedures cannot be initiated until IRB review and approval has taken place.

If you have any questions, please click on the IRB# (above) and contact the IRB analyst listed in the study workspace.

DHHS Federal Wide Assurance Identifier: FWA00000459

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**** *This memorandum constitutes official CHOP IRB correspondence.* ****